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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,766	11/20/2003	Fritz Kirchhofer	33728/US	8384

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EXAMINER

PRASAD, SONAL

ART UNIT PAPER NUMBER

3767

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/717,766	<b>Applicant(s)</b> KIRCHHOFFER, FRITZ	
	<b>Examiner</b> Sonal Prasad	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/17/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Novacek et al. (US 5,112,318). Novacek et al discloses the same invention as in claim 1, including a cannula support comprising a thread turning in a first direction and another thread turning in a second, generally opposite direction. (Claim 4). Novacek et al discloses the same invention as in claim 2, including the cannula support, wherein said thread turning in said first direction is an inner thread and said thread turning in said generally opposite direction is an outer thread. (Claims 4,11). Novacek et al discloses the same invention as in claim 3, including the cannula support comprising at least one latching element arranged on one of the inside and outside of said cannula support. (Claim 12) Novacek et al discloses the same invention as in claim 4, including a cannula system comprising a cannula support and a protective cap having a thread engageable with said thread turning in said second generally opposite direction (Fig. 8, #32). The cannula system comprising at least one latching element arranged on one of the inside and outside of said cannula support (Claim 12.) The system wherein said protective cap comprises at least one complementary latching element for latching with the latching element of the cannula support (Claim 12). Novacek et al discloses the same invention

as in claim 7, including the system wherein a second protective cap is arranged within said protective cap (Fig 25a, barrel 8). Novacek et al discloses the same invention as in claim 8, including the system comprising an injection device having a thread engageable with said thread turning in the first direction ((45)). Novacek et al discloses the same invention as in claim 9, including a cannula support comprising a protective cap, wherein at least one latching element is provided on said cannula support and at least one corresponding latching element is provided on said protective cap, the latching elements cooperating to create a latching connection between the cannula support and the protective cap. (Fig 4, Claim 15.)

Novacek et al discloses the same invention as in claim 14, including the cannula support, wherein at least one second latching element is provided on the cannula support and can engage with one of a corresponding counter element and the corresponding latching element on the protective cap to create a releasable connection between the cannula support and the protective cap. (Claims 4-6) Novacek et al discloses the same invention as in claim 15, including the cannula wherein the cannula support comprises connection element for connecting the cannula support to a pen which is inherent characteristic that this device is capable of performing and consists of this structure. Novacek et al discloses the same invention as in claim 16, including the cannula wherein said connection element creates a connection which requires a lesser force for releasing the connection than the force required for releasing the connection between the at least one latching element on the cannula support and the corresponding latching element on the protective cap which is also inherent. Novacek et

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al discloses the same invention as in claim 17, including the cannula support wherein said protective cap is more easily releasable from said cannula support than the cannula support is from the pen. (Fig 25a, Claim 12.) Novacek et al discloses the same invention as in claim 18, including a method for covering a cannula carried by a cannula support using a cannula protecting cap, wherein the cannula support comprises a latching element, and wherein the cannula is temporarily covered when the protecting cap is coupled to the cannula support but not to the latching element and permanently covered when the protecting cap is coupled to the latching element. (Claims 12 & 15). Novacek et al discloses the same invention as in claim 19, including a needle cover comprising a needle support carrying a needle, said needle support comprising a cam and an inside surface with an inside thread for coupling the support to an injection device, an inner protective cap coupled to the needle support; and an outer protective cap generally surrounding the inner protective cap and comprising a left-handed thread and a cavity on an inside surface, said needle support comprising a complementary counter thread whereby the outer protective cap and the needle support may be releasably connected to each other, said counter thread turning in a direction generally opposite to the inside thread, said cam received in said cavity after said needle support is coupled to the injection device. (Fig 4, Claim 15.)

2. Claims 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohammad M.B.B.S. (US 6,379,337). Mohammad et al discloses the same invention as in claim 9, including a cannula support comprising a protective cap, wherein at least one latching element is provided on said cannula support and at least one

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corresponding latching element is provided on said protective cap, the latching elements cooperating to create a latching connection between the cannula support and the protective cap. (Fig 4 & 5A). Mohammad et al discloses the same invention as in claim 10, including the cannula support wherein the latching elements cooperate to form a non-releasable latching connection. (Claim 4.) Mohammad et al discloses the same invention as in claim 11, including the cannula support wherein the protective cap can be coupled to the cannula support in such a way that there is no connection between the latching elements. (Claims 4 & 5) Mohammad et al discloses the same invention as in claim 12, including the cannula support wherein at least one latching element on the cannula support and the corresponding latching element on the protective cap is one of the group consisting of a cam, a circumferential ring, an element biased by a spring force, a recess and a through-hole. (Claims 4-6). Mohammad et al discloses the same invention as in claim 13, including the cannula wherein the at least one latching element is provided on a lateral, outer surface of the cannula support. (Fig 4, #8). Mohammad et al discloses the same invention as in claim 14, including the cannula support, wherein at least one second latching element is provided on the cannula support and can engage with one of a corresponding counter element and the corresponding latching element on the protective cap to create a releasable connection between the cannula support and the protective cap. (Claims 4-6).

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonal Prasad whose telephone number is 571-272-3383. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sonal Prasad  
Examiner  
Art Unit 3767

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KEVIN C. SIMONS  
PRIMARY EXAMINER